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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 15/00, 16/00, B65D 83/04, 85/42 — A1

(11) International Publication Number: WO 96/33759

(43) International Publication Date: 31 October 1996 (31.10.96)

(21) International Application Number: PCT/US96/03408

(22) International Filing Date: 13 March 1996 (13.03.96)

(30) Priority Data:
08/428,960 24 April 1995 (24.04.95) US

(71) Applicant: DURA PHARMACEUTICALS, INC. [US/US]; 5880 Pacific Center Boulevard, San Diego, CA 92121 (US).

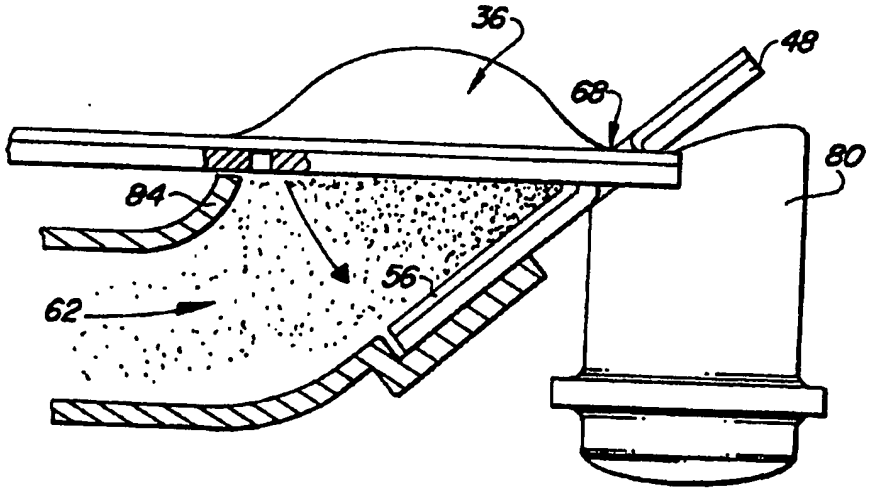
(72) Inventors: EISELE, Robert, F.; 25432 Fallen Oak Lane, Laguna Niguel, CA 92677 (US). CAMERON, Allan; 272 Entrada Drive, Santa Monica, CA 90402 (US). TITZLER, David; 753 Avenida Loma Portal, Newbury Park, CA 91320 (US). PORCHE, Leonard; 4756 Adam Road, Simi Valley, CA 93063 (US).

(74) Agents: OHRINER, Kenneth, H. et al.; Lyon & Lyon, Suite 4700, 633 West Fifth Street, Los Angeles, CA 90071-2066 (US).

(81) Designated States: AU, BG, BR, BY, CA, CN, CZ, FI, HU, JP, KP, KR, KZ, MN, MX, NO, NZ, PL, RO, RU, SG, SK, UA, VN, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

(54) Title: DRY POWDER INHALER DELIVERY SYSTEM



(57) Abstract

A powder storage and delivery system for a drug powder inhaler (20) has a carrier disk (46) with a blister shell (54) sealed by a shear layer (56). A tab (48) is adhered to the shear layer (56), underneath the blister shell (54). The carrier disk (46) is placed into a dry powder inhaler (20). An actuator (80) pushes against the tab (48), causing the shear layer (56) to tear away, releasing the powder drug contents (62) from the blister into the dry powder inhaler (20). A disk carrier (130) has bursting blisters (132) with a brittle blister shell (132) sealed with a foil lid (150), and covered by a plate (136). An actuator (160) moves against the plate (136), causing the plate (136) to buckle and the blister shell (132) to burst open, releasing powdered drug (62) into the dry powder inhaler (20).

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DESCRIPTION

DRY POWDER INHALER DELIVERY SYSTEM

BACKGROUND OF THE INVENTION

Field of the Invention

The field of the invention is dry powder storage devices and systems for powdered drugs.

Various drugs in a dry powder mixture form may be inhaled directly into the lungs, through the mouth or nose. Inhalation allows the drug to bypass the digestive system and may eliminate the need for other more interventional drug application techniques, e.g., hypodermic injections, etc. Direct inhalation, can in some cases, allow smaller doses of a drug to be used to achieve the same desired results as the same drug taken orally. In other cases, inhalation can help to avoid undesirable side effects.

To provide for direct inhalation of a powdered drug, various dry powder inhalers have been used. These dry powder inhalers typically deliver dry powder from a bulk reservoir, capsule, or blister package, for inhalation by the patient. For sealing the powdered drug from the environment (to reduce caking, contamination, etc.), individual discrete sealed dose containers, such as blisters are preferred. However, while various blister dry powder storage and delivery devices have been used, various disadvantages remain. For example, the blister must be strong enough to provide a good seal against the environment, but also be able to reliably release the drug powder when used by the patient. In addition, to better provide accurate doses, virtually of the drug powder must be released from the blister into the inhalation device, without, of course, allowing any of the blister or container material mix with or flow out with the drug powder. As inhaled drugs, such as asthma drugs, may be used very

frequently, the drug storage and delivery materials and device should advantageously be compact, low cost and easy to manufacture and use.

Accordingly, it is an object of the invention to provide an improved dry powder storage and delivery system, for use with an inhaler.

SUMMARY OF THE INVENTION

To these ends a dry powder storage and delivery device preferably includes a disk having radially spaced apart metal foil blisters containing a drug powder. The blisters are advantageously sealed onto an underlying metal foil shear layer. In the preferred embodiment, the shear layer is bonded onto a carrier disk. Shear tabs are advantageously bonded onto to the shear layer, underneath each blister, with a gap separating the tabs from the disk. In the preferred use, an actuator pushes on the tab, shearing or tearing out the shear layer from the blister, and releasing the dry powder contents of the blister.

The blister may also preferably be formed of a brittle material with a generally centrally located score line, so that the blister will burst open when engaged by an actuator, to release the powder drug contents of the blister.

BRIEF DESCRIPTION OF THE DRAWINGS

Other objects and features of the present invention will become apparent from the following detailed description taken together with the accompanying drawings. The drawings, however, are provided for illustration purposes only and are not intended as a limitation on the scope of the invention.

In the drawings, wherein similar reference characters denote similar elements throughout the several views:

Fig. 1 is a perspective view of a dry powder inhaler;

Fig. 1a is a perspective view of the advance knob of the inhaler of Fig. 1;

Fig. 1b is a plan view of the inhaler of Fig. 1;

Fig. 1c is a schematically illustrated partial section view of the inhaler of Fig. 1;

Fig. 2 is a perspective view of a drug carrier disk, having exterior tabs;

Fig. 3 is a perspective view of an alternative carrier disk, having interior disk tabs;

Fig. 4 is another disk carrier embodiment having tabs contained within the disk;

Fig. 5 is an enlarged partial section view taken along line 5-5 of Fig. 2;

Fig. 5A is a top view thereof;

Fig. 5B is an exploded section view taken along line 5B-5B of Fig. A;

Fig. 5C is a bottom view thereof;

Fig. 6 is a side elevation view thereof, just prior to opening the blister;

Fig. 7 is a side elevation view thereof, just after the blister has been sheared open;

Fig. 8 is a section view of the carrier disk of Fig. 2 installed within a first embodiment of a dry powder inhaler;

Fig. 9 is a section view of the disk carrier of Fig. 2 installed within a second embodiment dry powder inhaler;

Fig. 10 is a perspective view of an alternative disk carrier having bursting circumferentially scored blisters on angled plates;

Fig. 11 is an alternative disk carrier embodiment having radially scored bursting blisters on flat plates;

Fig. 11a a perspective view of the underside of the disk carrier of Fig. 11;

Fig. 12 is yet another disk carrier embodiment having circumferentially scored bursting blisters on flat plates;

Fig. 13 is a section view fragment taken along line 13-13 of the Fig. 10;

Fig. 14 is a side elevation view of the blister of Fig. 13, just prior to opening;

Fig. 15 is a side elevation view thereof, showing the blister immediately after opening; and

Fig. 16 is a perspective view of a straight strip carrier.

DETAILED DESCRIPTION OF THE DRAWINGS

Turning now in detail to the drawings, as shown in Fig. 1, a dry powder inhaler 20 has a mouthpiece 22 which is covered by a cap 24 when not in use. A knob 26 on top of the inhaler 20 may be used to advance individual drug doses for delivery through the mouthpiece 22. Referring to Figs. 1, 1b, and 1c, a blister opening mechanism 38 includes a center button 28 positioned over a spring 44 on a rocker arm 40. The rocker arm 40 has a lever end 42 for pushing up on an interior tab 32 on a carrier disk 34 to shear or tear open a blister 36.

The carrier disk 34 and blister 36 are further illustrated in Figs. 2-5. Fig. 2 shows a carrier disk 46 have exterior tabs 48 extending from radially spaced apart blisters 36 supported on a carrier disk 60. Fig. 3 better illustrates the carrier disk 34 shown in Fig. 1c, which has interior tabs 32. Fig. 4 shows another alternative carrier disk embodiment having tabs contained within the profile of the disk 50. Shear pin holes 52 extend through the disk 50, and in use, pins in an inhaler device extend through the holes 52 to push against a tab contained within the disk 50, to shear open the blisters 36. The carrier disks 34, 46 and 50 may include an indexing/drive notch 72.

Turning to Fig. 5 which illustrates an exterior tab carrier disk design, a blister shell 54 is positioned over a shear layer 56. The perimeter of the blister shell 54 is advantageously heat sealed to the shear layer 56 as

shown at 58 in Figs. 5 and 5a. Drug powder 62 is contained between the blister shell 54 and the shear layer 56. A tab 48 underlies the shear layer 56, below the blister shell 54. The tab 48 is separated from the disk carrier 60 by a gap 64 all around, except for at the hinge line 68 (Fig. 7). The hinge line 68 may optionally be provided as an indented area. A stress concentrator 70, can similarly be included as an option by providing a point or tooth on the disk carrier 60 at the innermost location of the gap 64, just inside of where the blister shell and shear layer join. The stress concentrator can help start the shearing/tearing action of the shear layer.

The blister shell 54 and shear layer 56 are preferably metal, e.g., aluminum, foils. The disk carrier 60 and tab 48 are preferably injection molded or die cut plastic. The shear layer 56 is adhered to the disk carrier 60 and tab 48 with an adhesive 49, and spans across the gap 64, as shown in Figs. 5B and 5C.

Figs. 6 and 7 illustrate operation of the disk carrier 60 within an inhaler. As shown in Fig. 6, the disk 60 rests on a support 84 positioned just inside of the gap 64. The blister 36 is positioned over a guide wall 86. As shown in Figs. 6 and 7, an actuator 80 pushes up on the tab 48, which, acting as a lever, causes the shear layer 56 (which forms the bottom surface of the blister 36) to shear and tear away from the blister shell 54, thereby opening the blister. The powder 62 contained within the blister 36 falls free of the blister 36 and disk 60, into a chute in the inhaler. The tab 48 pivots about the hinge point 68. As this occurs, the heat seal 58 remains intact, with the opening of the blister 36 provided by the tearing of the shear layer 56.

Referring to Fig. 8, a dry powder inhaler 100 has a housing 102, a mouthpiece 104 and an impeller 108 within a mixing chamber 106. A motor 110 powered by batteries 112 spins the impeller 104. As the blister 36 is sheared

open, as shown in Figs. 6 and 7, the powder from the blister **36** falls into the mixing chamber **106**, is mixed with air, and can be drawn out and inhaled by the patient. Fig. 9 shows an alternative inhaler embodiment having a centrally located mouthpiece **104**.

Figs. 10-16 illustrate blisters which are burst open, rather than torn or sheared open. As shown in Fig. 10, a bursting blister carrier disk **130** has a plurality of bursting blisters **132** on angled plates **136**. The plates **136** and blisters **132** have a circumferential score **134**.

Fig. 12 shows a similar embodiment, but with the plates flat in the plane of the disk rather than angled.

Fig. 11 shows an alternative embodiment having flat plates **144**, with a radial score **142** on the plates **140** and blisters. Fig. 11a better illustrates the radial scored blisters **148** on the flat radially scored plates **144**. The score or weakened section of the plates **144** and the blisters **142** are preferably centrally located on each blister **148**.

As shown in Fig. 13, a bursting blister carrier disk **130** has a brittle blister shell **132** attached by a heat seal **58**, at the blister shell perimeter, to a lid stock **150**. The lid stock **150** in turn is bonded onto a plate **136**. The blister shell **132** has a score or weak point **134** at its center. Correspondingly, the plate **136** has a score aligned with the score **134** on the blister shell **132**.

The blister shell **132** is advantageously made from a brittle plastic or metal material. The lid stock **150** is preferably a metal (e.g., aluminum foil), while the plate **136** is preferably a hard injection molded or die cut plastic, as is the carrier disk center section.

In use, as shown in Figs. 14 and 15, a plunger or actuator **160**, having a broad flat blade shape with an angled point **166** is driven down onto the score **134** on the plate **136** which is supported at its sides by supports **164** (part of the inhaler). As the actuator is driven into the

blister, the blister cracks or bursts open, as shown in Fig. 15, releasing the powder 62.

The blisters shown in Figs. 5 and 13 may also be provided in a strip form, rather than a disk form, as shown in Fig. 16.

Thus, while several embodiments have been shown and described, it should be appreciated that many more modifications may be made, without departing from the spirit and scope of the present invention.

WE CLAIM:

1. A powder storage and delivery system for a dry powder inhaler, comprising:

a carrier;

a blister shell on the carrier;

a shear layer attached around the perimeter of the blister shell; and

a tab attached to the shear layer.

2. The system of claim 1 wherein the carrier is a disk.

3. The system of claim 1 wherein the carrier is a strip.

4. The system of claim 1 wherein the shear layer comprises a metal foil.

5. The system of claim 1 wherein the blister shell comprises a metal foil.

6. The system of claim 1 wherein the shear layer is attached to the carrier and to the tab.

7. The system of claim 1 wherein the blister shell extends over the carrier.

8. A powdered drug storage and delivery system comprising:

a carrier disk;

a tab;

a shear layer attached to and connecting the carrier disc to the tab;

a blister attached to the shear layer, on the tab.

9. The system of claim 8 wherein a gap separates the carrier disk and the tab.

10. A dry powder delivery system for an inhaler, comprising:

a carrier;

a plate on the carrier;

a blister shell attached to the plate around the perimeter of the blister shell;

a score line centrally located on the blister shell; and

a dose a powdered drug within the blister shell.

11. The system of claim 10 wherein the blister shell comprises a brittle material.

12. A powdered drug storage and delivery system comprising:

a round carrier disk having a central opening;

a plurality of shear tabs radially projecting from the central opening, each shear tab having a circumferential edge spaced apart from the carrier disk across a gap, and with each shear tab pivotably connected to the carrier disk at a hinge line along one side of the tab;

a shear layer overlying, attached to, and connecting the carrier disc and the shear tabs; and

a blister layer overlying and attached to the shear layer, the blister layer including a plurality of blister shells forming a powder containing space in between the shear layer and the blister shells, and with one blister shell formed on substantially each tab.

13. The powder drug storage and delivery system of claim 12 further comprising a stress concentrator at the circumferential edge of the tab, opposite from the hinge line.

14. The powder drug storage and delivery system of claim 12 further comprising a heat seal around a perimeter of substantially each blister shell, attaching the blister layer to the shear layer.

15. The dry powder delivery system of claim 10 wherein the carrier has a central opening and the score line extends radially outwardly from the central opening.

16. The dry powder delivery system of claim 10 wherein the carrier comprises a disc and the score line extends generally parallel to the perimeter of the disc.

17. The dry powder delivery system of claim 10 wherein the carrier comprises a strip.

18. The dry powder delivery system of claim 10 wherein the plate is co-planer with the disc.

19. The dry powder delivery system of claim 10 further comprising a score line on the plate aligned with the score line on the blister shell.

20. The dry powder delivery system of claim 10 further comprising a lidstock bonded on to the plate and a heat seal joining the blister shell to the lidstock.

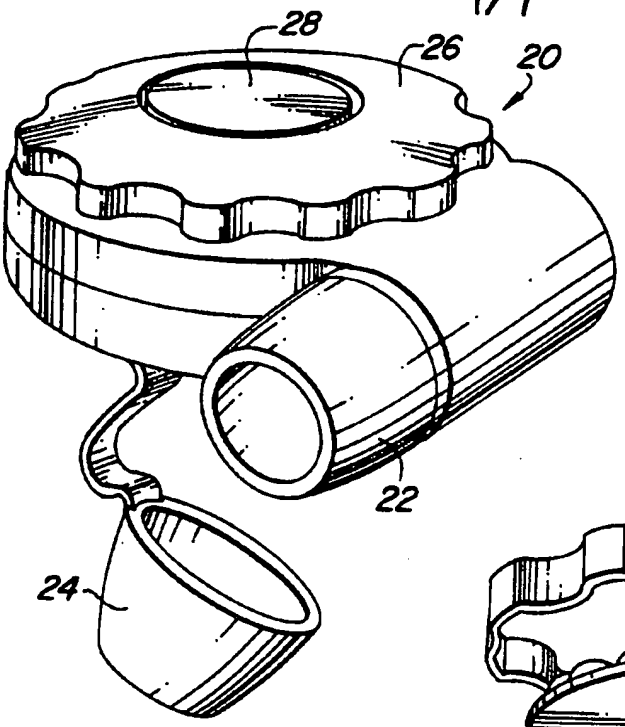


Fig. 1

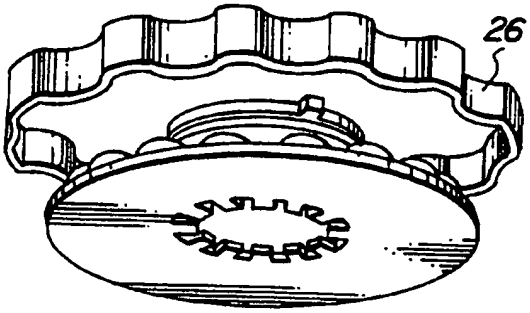


Fig. 1A

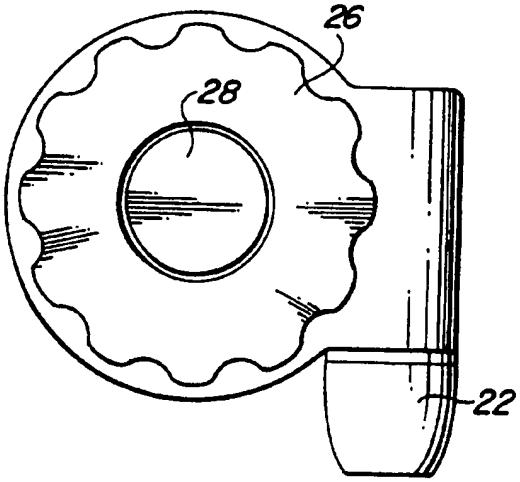


Fig. 1B

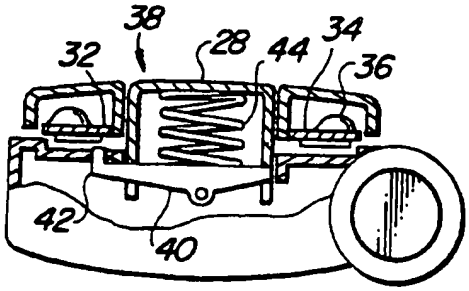


Fig. 1C

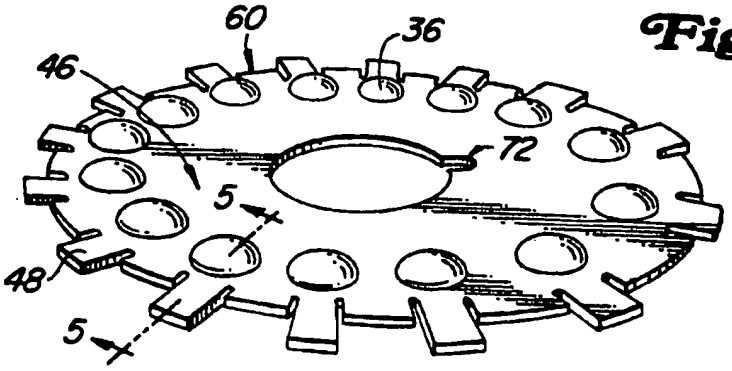


Fig. 2

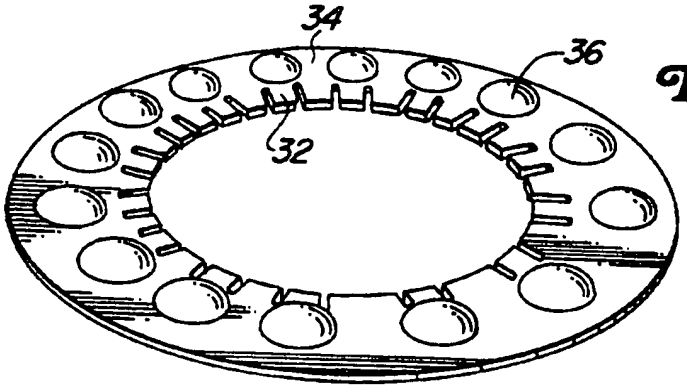


Fig. 3

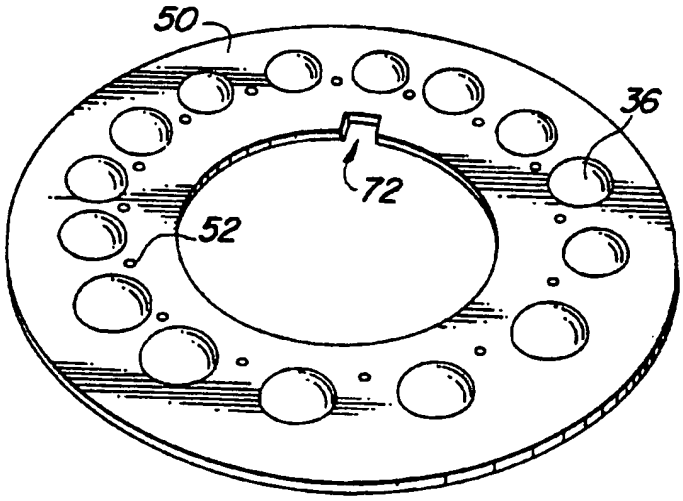


Fig. 4

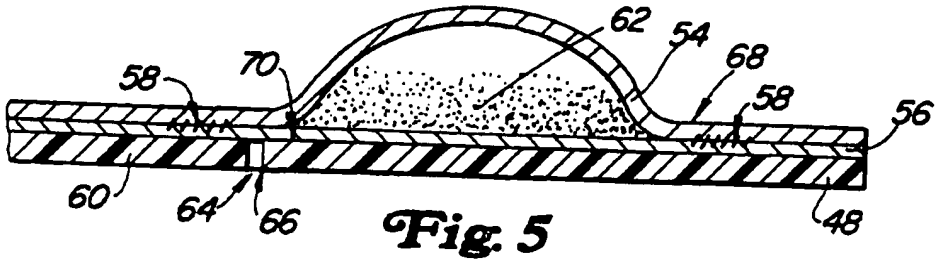
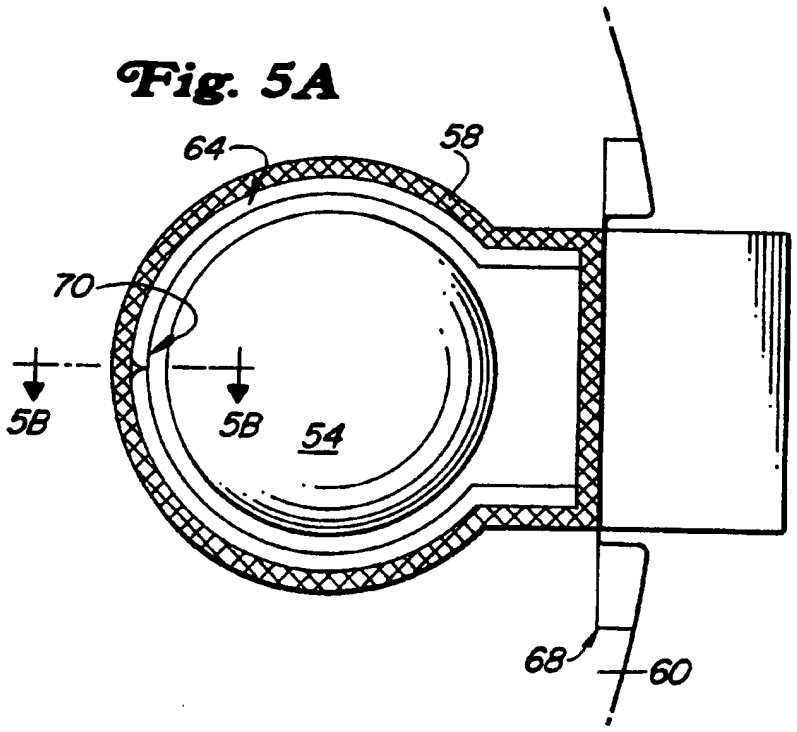


Fig. 5

Fig. 5A



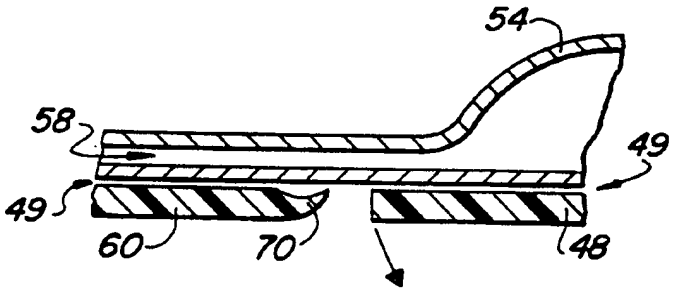


Fig. 5B

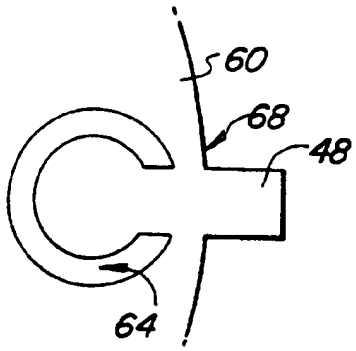


Fig. 5C

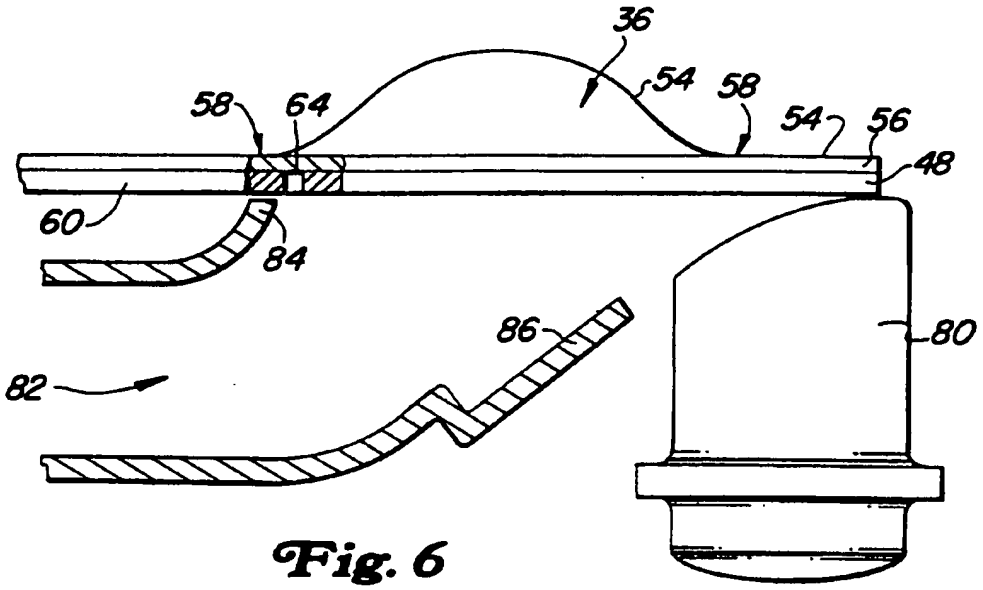


Fig. 6

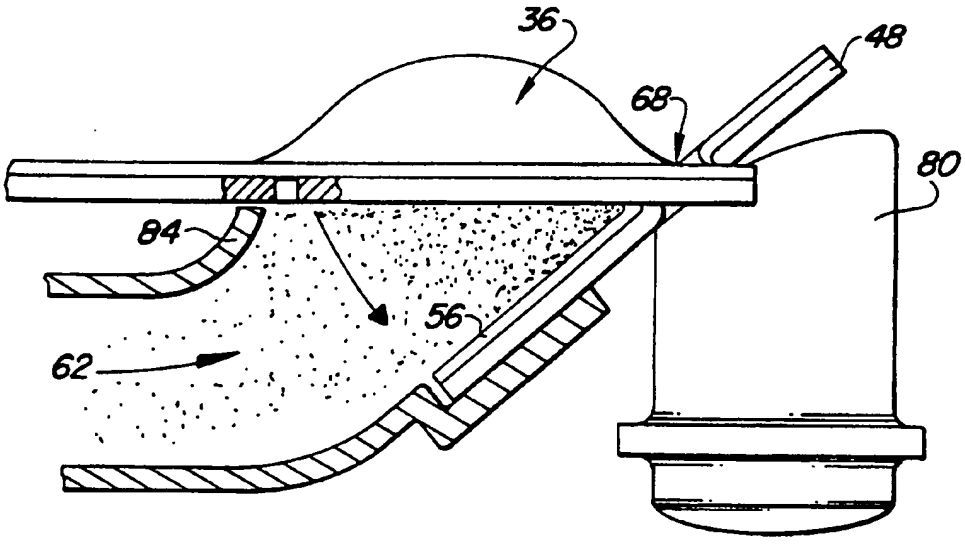


Fig. 7

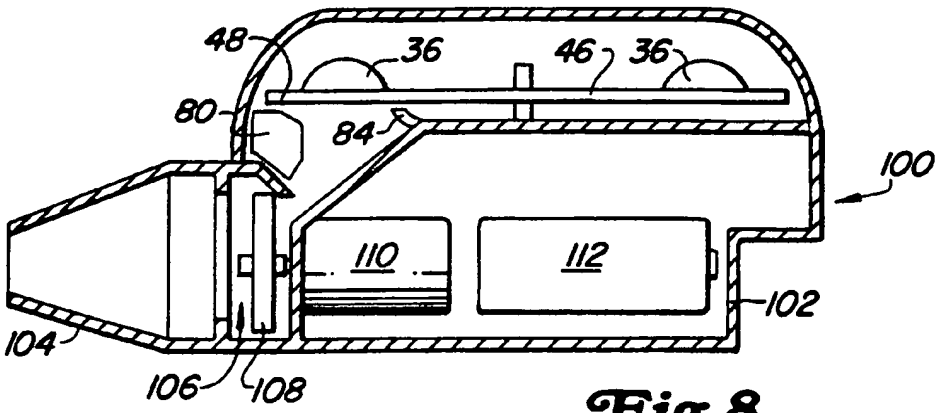


Fig. 8

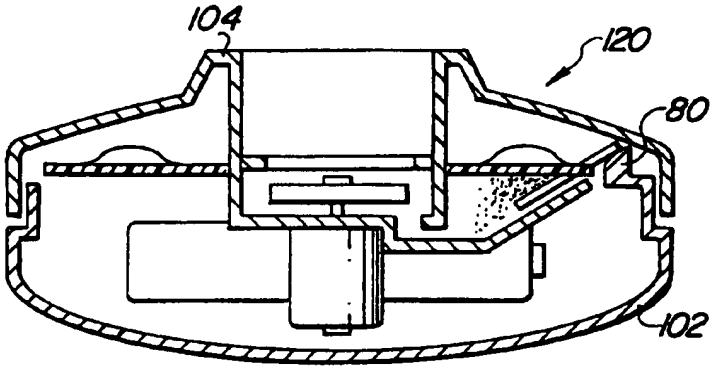


Fig. 9

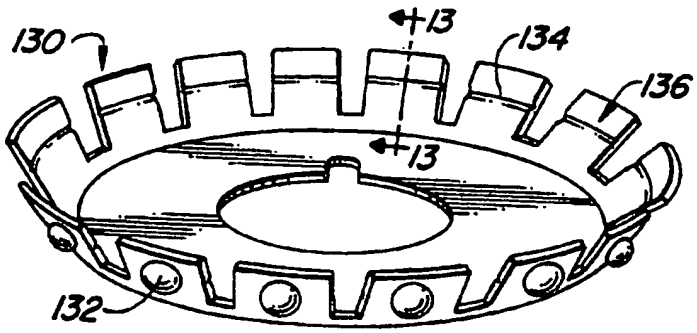


Fig. 10

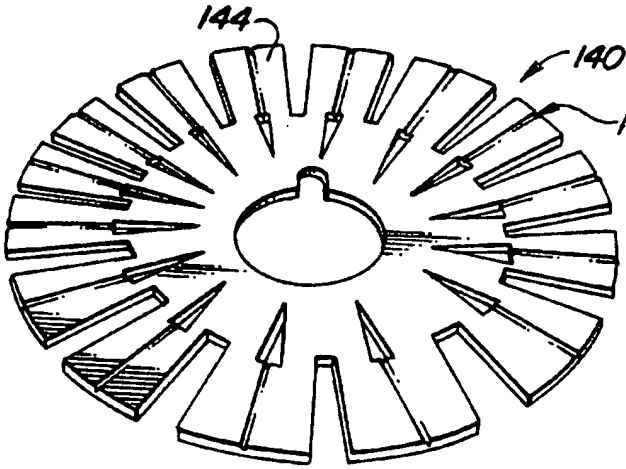


Fig. 11

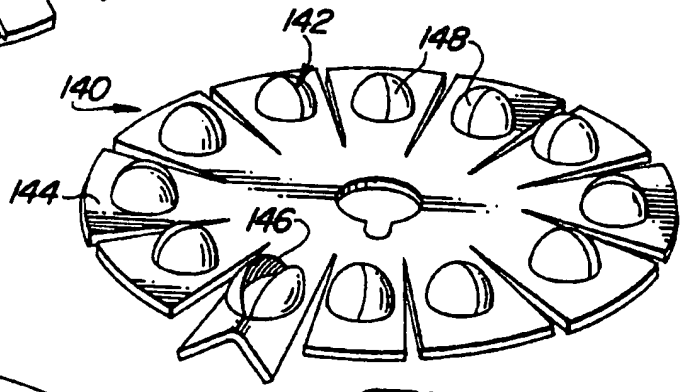


Fig. 11A

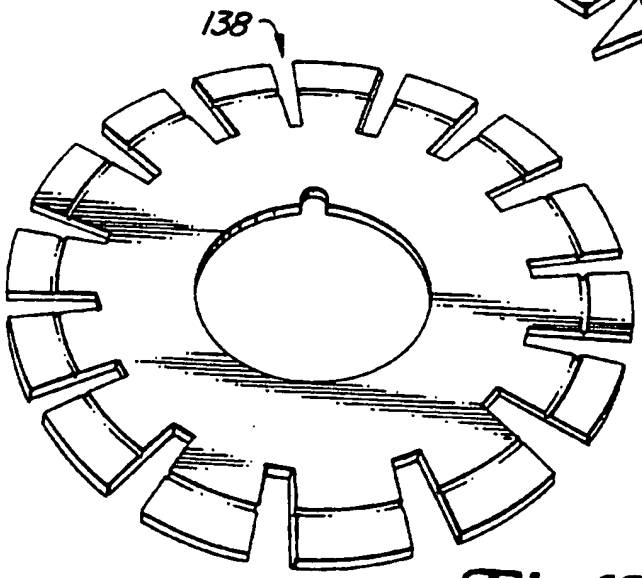


Fig. 12

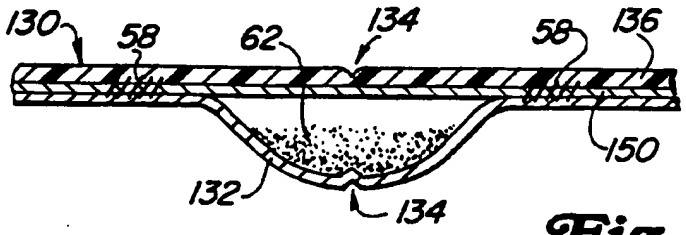


Fig. 13

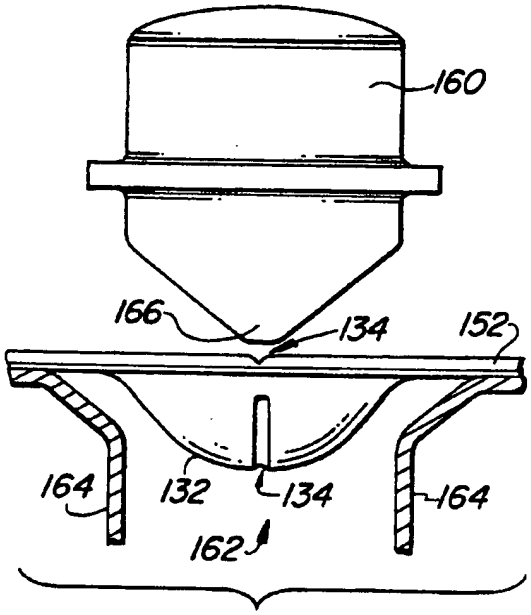
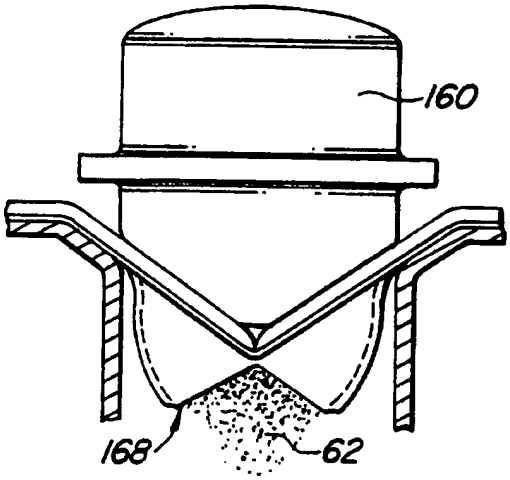


Fig. 14

Fig. 15



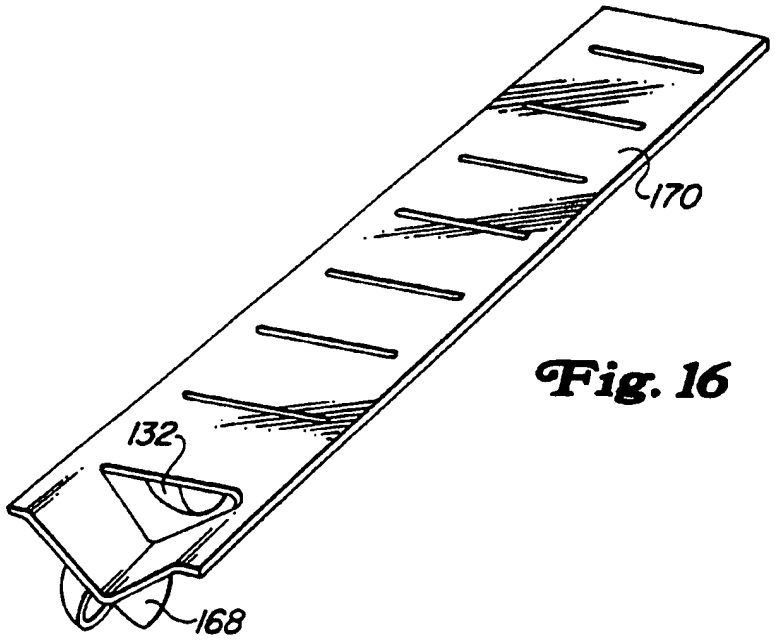


Fig. 16

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/03408

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 15/00, 16/00; B65D 83/04, 85/42
US CL :128/ 203.15, 203.21; 206/ 531, 532

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/ 203.15, 203.21; 206/ 531, 532

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO, A, 92/04069 (KALLSTRAND ET AL.) 19 March 1992. see entire document	1, 3-7
Y	US, A, 4,778,054 (NEWELL ET AL.) 18 October 1988, see Fig. 1.	2, 8, 9-11, 15-20
Y	US, A, 4,294,361 (MARGULIES ET AL.) 13 October 1981. see entire document	8, 9
Y	US, A, 3,759,371 (MARKS) 18 September 1973. see entire document	10, 11, 15-20

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be part of particular relevance

"E" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 MAY 1996	21 JUN 1996
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer AARON J. LEWIS
Facsimile No. (703) 305-3230	Telephone No. (703) 308-0716

Form PCT/ISA/210 (second sheet)(July 1992)*